



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0429; FRL-9902-15]

Quinclorac; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of quinclorac in or on rapeseed, subgroup 20A. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0429, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0429 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0429, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 25, 2012 (77 FR 43562) (FRL-9353-6), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8035) by BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.463 be amended by establishing tolerances for residues of the herbicide quinclorac (3,7-dichloro-8-quinolinecarboxylic acid), in or on rapeseed, subgroup 20A at 1.0 parts per million (ppm). That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA has revised this tolerance level based on analysis of the residue field trial data using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures. The reason for this change is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there

is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for quinclorac including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with quinclorac follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Quinclorac has low acute toxicity by oral, inhalation, and dermal routes of exposure. It is minimally irritating to the eye and non-irritating to the skin. Quinclorac is a skin sensitizer.

Subchronic toxicity includes, decreased body weight gains, increased water intake, increased liver enzymes, and focal chronic interstitial nephritis (rats). Chronic toxic effects include body weight decrement, increase in kidney, and liver weights, and hydropic degeneration of the kidneys (dogs). At high doses, chronic toxicity also includes increased incidences of pancreatic acinar cell hyperplasia, and adenomas (rats). Neurotoxic effects were not observed in any of the acute, subchronic and chronic studies with quinclorac.

There was no increased qualitative or quantitative fetal or offspring susceptibility in the prenatal developmental or postnatal reproduction studies. Developmental toxicity in the rabbit consisted of increased resorptions, post-implantation loss, decreased number of live fetuses, and reduced fetal body weight. These effects occurred at much higher doses than the maternal effects of decreased food consumption, and increased water consumption, and decreased body weight gain. In the rat, no developmental toxicity was observed at the highest dose tested (HDT) (438 milligrams/kilogram/day (mg/kg/day)). In the 2-generation reproduction study, parental toxicity and offspring toxicity occurred at the same dose. Parental toxicity consisted of reduced body weight in both sexes during pre-mating and lactation periods. Offspring toxicity consisted of decreased pup weight, developmental delays and a possible marginal effect on pup viability. No reproductive toxicity occurred at the HDT (480 mg/kg/day).

There are no mutagenicity concerns. Quinclorac is not mutagenic in bacterial assays and does not cause unscheduled DNA damage in primary rat hepatocytes. There is also no evidence of a genotoxic response in whole animal test systems (*in vivo* mouse bone marrow micronucleus assay). Quinclorac was negative in a mammalian cell *in vitro*

cytogenetic chromosomal aberration assay in Chinese hamster ovary cells (CHO).

Quinclorac produced an equivocal increase in the incidence of one type of benign tumor (pancreatic acinar cell adenomas) in only one sex of one species of animals (male Wistar rats). There was no evidence of carcinogenicity in mice or female rats. Based on this limited evidence of cancer, a quantification of cancer risk is not warranted because the chronic reference dose (RfD) will adequately account for all chronic effects, including carcinogenicity, likely to result from exposure to quinclorac.

Neurotoxic effects were not observed in any of the acute, subchronic and chronic studies with quinclorac. Due to lack of evidence of neurotoxic effects, the Agency has determined that no acute, subchronic, or developmental neurotoxicity studies are required for quinclorac.

Specific information on the studies received and the nature of the adverse effects caused by quinclorac as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Quinclorac: Risk Assessment to Support Permanent Tolerance for Rapeseed Subgroup 20A without U.S. Registration” in docket ID number EPA-HQ-OPP-2012-0429.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOC) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a

Careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a RfD - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for quinclorac used for human risk assessment is shown in Table 1 of this unit.

Table 1--Summary of Toxicological Doses and Endpoints for Quinclorac for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 200 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Acute RfD = 2.0 mg/kg/day aPAD = 2.0 mg/kg/day	Developmental toxicity study in rabbits LOAEL = 600 mg/kg/day based on increased early resorptions and postimplantation loss, decreased live fetuses, decreased fetal body weight. These fetal effects are presumed to occur after a single dose
Acute dietary (General population including infants and children)	None	None	No acute dietary endpoint selected based on the absence of an appropriate endpoint attributed to a single dose

Chronic dietary (All populations)	NOAEL= 37.5 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.38 mg/kg/day cPAD = 0.38 mg/kg/day	Carcinogenicity study in mice LOAEL = 150 mg/kg/day based on decreased body weight
Incidental oral short-term (1 to 30 days)	NOAEL= 70 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	LOC for MOE = 100	Developmental toxicity study in rabbits LOAEL = 200 mg/kg/day based on decreased maternal body weight gain, and food consumption, and increased water consumption
Dermal short-term (1 to 30 days)	None	None	No adverse effects were seen in dermal studies
Dermal intermediate-term (1 to 6 months)	None	None	Same
Inhalation short- term (1 to 30 days) and intermediate- term (1 to 6 months)	Inhalation (or oral) study NOAEL= 70 mg/kg/day (inhalation absorption rate = 100%) UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Developmental toxicity study in rabbits Maternity toxicity LOAEL = 200 mg/kg/day based on decreased maternal body weight gain and food consumption, and increased water consumption
Inhalation (1 to 6 months)	None	None	Long-term inhalation exposure is not anticipated under current use scenarios
Cancer (Oral, dermal, inhalation)	Quantification of risk using the chronic RfD will adequately account for all chronic effects, including carcinogenicity, which may result from exposure to quinclorac.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. Mg/kg/day = milligrams/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to quinclorac, EPA considered exposure under the petitioned-for tolerances as well as all

existing quinclorac tolerances in 40 CFR 180.463. EPA assessed dietary exposures from quinclorac in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for quinclorac. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, the acute dietary assessment assumes 100% crop treated (PCT) along with tolerance or maximum residue level estimates for quinclorac and its methyl ester metabolite. It used dietary exposure evaluation model (DEEM) default processing factors and an empirical processing factor for oil commodities of rapeseed subgroup 20A.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA 2003-2008, NHANES/WWEIA. As to residue levels in food, the chronic dietary assessment used the same residue levels, processing factors and 100 PCT assumptions used in the acute dietary assessment.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to quinclorac. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for quinclorac. Tolerance or

maximum residue levels for quinclorac and its methyl ester metabolite and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for quinclorac in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of quinclorac. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier I Rice Model, Version 1.0, the estimated drinking water concentrations (EDWCs) of quinclorac for surface water are estimated to be 511 parts per billion (ppb) for acute and chronic exposures. Based on the screening concentration in ground water (SCI GROW) model, the EDWCs for ground water are estimated to be 29 ppb for acute and chronic exposures. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute and chronic dietary risk assessments, the water concentration value of 511 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Quinclorac is currently registered for the following uses that could result in residential exposures: Turf grass and ornamentals. EPA assessed residential exposure using the following assumptions: Short-term inhalation exposures for residential handlers from mixing, loading, and applying quinclorac to residential turf, and short-term

postapplication incidental oral exposures (hand-to-mouth activities) of children from contact with treated turf. Intermediate-term exposures resulting from adult handler and postapplication exposures were not assessed due to a lack of a dermal POD. Incidental oral scenarios for children are considered to be short-term only. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. Cumulative effects from substances with a common mechanism of toxicity.

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found quinclorac to share a common mechanism of toxicity with any other substances, and quinclorac does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that quinclorac does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicology database for quinclorac consists of developmental toxicity studies in rats and rabbits and a 2-generation reproduction study in rats. There is no indication of increased qualitative or quantitative susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity data.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings.

- i. The toxicity database for quinclorac is complete.
- ii. There is no indication that quinclorac is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence that quinclorac results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on tolerance or maximum residue levels for residues of concern and assumed 100 PCT. EPA made conservative

(protective) assumptions in the ground and surface water modeling used to assess exposure to quinclorac in drinking water. EPA used similarly conservative assumptions to assess incidental oral exposures (hand-to-mouth activities) of toddlers to quinclorac. These assessments will not underestimate the exposure and risks posed by quinclorac.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to quinclorac and its methyl ester metabolite will occupy 1.6% of the aPAD for females age 13 to 49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to quinclorac and its methyl ester metabolite from food and water will utilize 8.9% of the cPAD for infants less than 1 year of age, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of quinclorac is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Quinclorac is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to quinclorac.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,100 for adults and 1,600 for children 1 to 2 years old. Because EPA's LOC for quinclorac is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, quinclorac is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for quinclorac.

5. *Aggregate cancer risk for U.S. population.* As explained in Unit III.A., the cPAD is protective of all effects, including carcinogenicity. Based on the chronic risk assessment described in Unit III.E.2., there is no concern for any potential carcinogenic effects from quinclorac.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to quinclorac residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology for quinclorac (liquid chromatography with tandem mass spectrometric detection (LC/MS/MS) method (BASF method D9708/1) and quinclorac methyl ester LC/MS/MS method (BASF method D9806/02) are available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is

recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for quinclorac.

C. Revisions to Petitioned-For Tolerances

Based on the data submitted with the petition, EPA is revising the proposed tolerances in or on rapeseed subgroup 20A from 1.0 ppm to 1.5 ppm. The Agency revised this tolerance level based on analysis of the residue field trial data using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures. Additionally, the Agency determined that the tolerance expression for proposed tolerance on rapeseed subgroup 20A should include quinclorac methyl ester.

The qualitative nature of quinclorac residues in plants was considered adequately understood for the currently registered crops, based upon the metabolism studies on rice, sorghum, and wheat. Additional metabolism data were submitted for quinclorac on canola to support use on rapeseed. This study showed a significant level of quinclorac methyl ester. The qualitative nature of quinclorac residues in livestock is also understood based upon the adequate goat and poultry metabolism studies. In earlier risk assessments, EPA had concluded that parent is the only residue of concern in both plant and livestock commodities for purposes of the tolerance expression and risk assessment. For the current action, because of the significant level of quinclorac methyl ester found, the Agency concluded that the residue of concern on canola is quinclorac and its methyl ester.

V. Conclusion

Therefore, tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the following commodity. Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, and its methyl ester, methyl-3,7-dichloro-8-quinolinecarboxylate, calculated as the stoichiometric equivalent of quinclorac, in or on rapeseed, subgroup 20A at 1.5 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final

rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal

Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 22, 2013

Daniel J. Rosenblatt,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In §180.463:

- a. Designate the text of paragraph (a) as paragraph (a)(1).
- b. Add new paragraph (a)(2).

The amendments read as follows:

§ 180.463 Quinclorac; tolerances for residues.

(a) * * *

(2) Tolerances are established for residues of the herbicide quinclorac, including its metabolites and degradates, in or on the commodity in the following table.

Compliance with the tolerance levels specified in this paragraph is to be determined by measuring only quinclorac, 3,7-dichloro-8-quinolinecarboxylic acid, and its methyl ester, methyl-3,7-dichloro-8-quinolinecarboxylate, calculated as the stoichiometric equivalent of quinclorac, in or on the commodity.

Commodity	Parts per million
Rapeseed, subgroup 20A ¹	1.5

¹ There are no U.S. Registrations.

* * * * *

BILLING CODE 6560-50-P

[FR Doc. 2013-28640 Filed 11/27/2013 at 8:45 am; Publication Date: 11/29/2013]